K053444

10. Certification
10.1 Summary for public disclosure

JUN - 9 2006

Submitter information:

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan Phone: +81-3-3279-7329 Fax: +81-3-3279-7541
Contact:	Shigeru Takimoto Research and development section Phone: +81-53-428-5712 FAX: +81-53-428-5719
Date summary prepared:	December 5, 2005

Device identification:

Device trade name:	KOWA KT-800
Classification name:	TONOMETER, AC-POWERED
Product code:	HKX

Intended use:

The KOWA KT-800 is indicated for measuring intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

Comparison:

As a substantial equivalent device, Kowa Automated Tonometer KT-500 is chosen. In Table 10.1, regulation information of Kowa Automated Tonometer KT-500 is shown and in Table 10.2, detail information of the device is shown.
KOWA KT-800 and Kowa automated Tonometer KT-500 have the same intended used and the similar to technological characteristics.

Kowa Automated Tonometer KT-500 is a non-contact tonometer with two direction automated alignment ability, up and down duration and left and right direction alignment. In addition, Kowa Automated Tonometer KT-500 can measure the intraocular pressure automatically by blowing the air to the subject eye.

KOWA KT-800 has an auto alignment ability of back and forth direction in addition to the same ability as the predicate device.

KOWA KT-800 delivers safety equivalent to that of the predicate device. The comparison of the devices are provided in Table 10.2.

Performance data:

KOWA KT-800 was tested the following terms and conformed to all specific requirements based on standards. KOWA KT-800 is equivalent to the predicted device.

Electrical safety

KOWA KT-800 was tested in accordance with IEC60601-1: 1988, Amendment 1:1991 and Amendment 2: 1995, and met to all requirements of standard and amendments.

Electromagnetic compatibility

KOWA KT-800 was tested in accordance with IEC60601-1-2: 2001, and met to all requirements of standard.

Risk management

KOWA KT-800 was evaluated in accordance with ISO14971: 2000, and met to all requirements of standard. The risk management of the device were deemed satisfactory. Remaining risks will be noted in the user manual, so users will be able to avoid them.

Test requirements and test procedure for ophthalmic instruments

KOWA KT-800 was tested in accordance with ISO15004: 1997 and was found to meet all requirements of the standard. For optical hazard, KOWA KT-800 was evaluated in accordance with IEC60825-1: 1993 and amendments, A1: 1997 and A2: 2001.The results were Class 1.

Test requirements and test procedure for tonometer

KOWA KT-800 was evaluated in accordance with ISO8612: 2001 and was found to meet all requirements of the standard.

Conclusion:

KOWA KT-800 is equipped with the fundamental technology features equivalent to the predicate device, and also delivers the equivalent level of safety.
Thus it is concluded that there is no difference in the basic functions and safety between KOWA KT-800 and the predicate device.

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Table 10.1: Predicate device

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Kowa Automated Tonometer KT-500	Kowa Company, Ltd.	K013805	10/11/2002

Table 10.2: Predicate device comparison

	Submitted device	**Predicate device**
Device name	KOWA KT-800	Kowa Automated Tonometer KT-500
Intended use	For measuring intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.	For the measurements of intraocular pressure to aid in the diagnosis of glaucoma.
Measuring function		
Measuring range	same	0 to 60mmHg
Measuring accuracy	same	+/-1mmHg for 0 to 30mmHg less +/- 2mmHg for 30mmHg to 60mmHg
Measurement time	same	within 100milisecond
Working distance	same	11mm
Automatic alignment function	**2D auto alignment:** Horizontal & vertical direction **3D auto alignment:** Horizontal & vertical direction, and forward & backward **Manual alignment:** Manual alignment	**2D auto alignment:** Horizontal & vertical direction **Manual alignment:** Manual alignment
Automatic measurement function	same	Automatic air blow manual air blow
Moving range for measurement head	Up/Down: +/- 3mm Right/Left: +/- 3mm Forward/Backward +/- 3mm	Up/Down: +/- 3mm Right/Left: +/- 3mm
Fixation light	same	Internal green LED
Display and Printer		
Display	5.6 inch color TFT monitor	5 inch B&W CRT monitor
Printer	same	58mm wide thermal line printer
Power specification and dimension		
Dimension	274mm(W) x 457mm(L) x 458mm(H)	260mm(W) x 450mm(L) x 450mm(H)
Weight	18kg	17kg
Power supply	AC 100V to 230V, 50/60Hz	AC 100 to 240V, 50/60Hz
Power consumption	60VA	65VA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Kowa Co. Ltd.
c/o Shinichi Yamanaka, Cosmos Corporation
319 Akeno
Obata-Cho, Watarai-Gun
Mie-Ken,
Japan 519-05

Re: K053444
Trade/Device Name: Kowa KT-800
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer
Regulatory Class: Class II
Product Code: HKX
Dated: May 25, 2006
Received: May 30, 2006

Dear Mr. Yamanaka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if know): K053444

Device Name: KOWA KT-800

Indications for Use:

The KOWA KT-800 is indicated for measuring intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device

Clay R. Batteman

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K053444